

## **REMARKS/ARGUMENTS**

Claims 1 and 5-9 are pending. Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

### **Drawing Objections**

The drawings filed in response to the Office Action of February 5, 2008 were not accepted for allegedly not being supported by the originally filed application. The Applicant traverses this allegation on non-support.

In the Office Action of February 5, 2008 the drawings were objected to for not showing every feature of the invention specified in the claims, namely, an o-ring and a port including a lock. FIG. 1 was amended to illustrate the o-ring within a leg of the Y-arm port as discussed at page 8 lines 4 to 7 which states”

**FIG. 2** shows the sleeve **10** disposed within the Y-arm port **60**. In this embodiment, the sleeve **10** will pass through the Y-arm port **60** and will protect the stent **20** until it is removed when the stent **20** is at the desired position. In other embodiments, the outer diameter of sleeve **10** is greater than the inner diameter of an o-ring in the Y-arm, and will therefore not pass through the o-ring.

**FIG. 1** shows the sleeve **10** prior to entry into a leg of a Y-arm port **60**.

FIG. 1 was amended to include an O-ring in the Y-arm as detailed in the above passage of the Applicant's original Detailed Description. Thus, no new matter has been added with the amendment to the figures. For these reasons, the withdrawal of the objections to the figures and acceptance of the figures is respectfully requested.

35 U.S.C. §112 Rejections

Claims 1, 5-9 and 21 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Claim 1 has been amended to more clearly reflect the Applicant's Detailed Description and accompanying figures.

Specifically, claim 1 has been amended to recite "a port to a vessel, the port including an o-ring having an o-ring inner diameter, wherein *a proximal portion of the sleeve is positioned proximal to the o-ring* and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter." For this reason, the rejection of claims 1, 5-9 and 21 under §112, first paragraph is requested.

35 U.S.C. §102 Rejections

Claims 1, 5, 7 and 8 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,270,521 to Fischell et al., (the Fischell patent). The Applicant traverses this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant this §102 rejection, the reference cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the Fischell patent fails to include each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §102(b). *See* MPEP 2131.

The Applicant asserts that the Fischell patent fails to disclose, teach, or suggest a system including a catheter; a stent assembly coupled to the catheter; the stent assembly comprising a coated stent including a stent framework and a drug coating disposed on at least a portion of the stent framework, a protective sleeve removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal

inner diameter; and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment assembly, and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open, wherein the protective sleeve is removed from covering the stent framework prior to deploying the stent, and a port to a vessel, the port including an o-ring having an o-ring inner diameter, the o-ring disposed at a distal end of the port wherein a proximal portion of the sleeve is positioned proximal to the o-ring and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, as recited in claim 1.

The Examiner alleges that Fischell teaches a system for treating a vascular condition comprising “a port to a vessel (18), the port including an o-ring having an o-ring inner diameter (portion of 18 acts as an o-ring), wherein a proximal portion of the sleeve (34) is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter (Fig. 2c)” (see, page 4 of the Final Office Action dated August 22, 2008). Further, in Response to Arguments the Examiner alleges that “a portion of element 18 of Fischell, a balloon, acts as an o-ring (the proximal end is a port, the distal end an o-ring)” (see page 6 of the Final Office Action dated August, 22, 2008).

FIG. 2C of the Fischell patent illustrates an angioplasty catheter 20 having an angioplasty balloon 18 and a slidable sheath 30 having an ultra-thin section 34, the sheath coaxially situated about the balloon angioplasty catheter 20 (see col. 3 lines 58-63 and col. 4 lines 17-18 and 36-37). Nowhere within the Fischell patent does it teach that angioplasty balloon 18 comprises a port to a vessel as that term is understood by one with ordinary skill in the art and as claimed and described by the Applicant. Further, nowhere within the Fischell patent does it teach that angioplasty balloon 18 has a portion that “acts as an o-ring” as alleged by the Examiner. Furthermore, nowhere within the Fischell patent does it teach that a proximal portion of sleeve 34 is positioned proximal to a port vessel. In fact nowhere within the Fischell patent does it teach or suggest these

limitations. For at least these reasons, the Fischell patent does not anticipate claim 1 or any claim depending therefrom.

Claims 5, 7 and 8 depend from claim 1 and include all of the limitations of that claim. Thus for at least this reason, claims 5, 7 and 8 are not anticipated by the Fischell patent. For these reasons, the withdrawal of the rejection of claims 1, 5, 7 and 8 under 35 U.S.C. § 102(b) is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

A. Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Fischell patent

The Applicant traverses this rejection. The Applicant respectfully asserts that the Fischell patent fails to disclose, teach, or suggest all the claim limitations of dependent claim 6.

As noted above, the Fischell patent does not teach or suggest all of the claim limitations of claim 1. Specifically, the Fischell patent does not teach or suggest, at least, the port including an o-ring having an o-ring inner diameter, the o-ring disposed at a distal end of the port wherein a proximal portion of the sleeve is positioned proximal to the o-ring and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, as recited in claim 1.

Claim 6 depends from independent claim 1 and includes all the elements and limitations of that independent claim. The Applicant therefore respectfully submits that dependent claim 6 is allowable over the Fischell patent for at least the same reasons as set forth above with respect to independent claim 1.

The withdrawal of the rejection of claim 6 as being unpatentable over the Fischell patent is respectfully requested.

B. Claim 9 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Fischell in view of Roberts

This rejection is traversed. As noted above in section A, the Fischell patent does not teach or suggest all of the claim limitations of claim 1. Specifically, the Fischell patent does not teach or suggest, at least, the port including an o-ring having an o-ring inner diameter, the o-ring disposed at a distal end of the port wherein a proximal portion of the sleeve is positioned proximal to the o-ring and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter, as recited in claim 1. The Roberts patent does not cure this defect. At most, the Roberts patent teaches a sleeve having a proximal portion that has an outer diameter the same as the medial portion of the sleeve. Thus, Fischell in view of Roberts does not teach or suggest all of the claim limitations of independent claim 1.

Claim 9 depends from independent claim 1 and includes all the elements and limitations of that independent claim. The Applicant therefore respectfully submits that dependent claim 9 is allowable over Fischell in view of Roberts for at least the same reasons as set forth above with respect to independent claim 1. The withdrawal of the rejection of claim 9 as being unpatentable over Fischell in view of Roberts is respectfully requested.

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## **Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5021.

Respectfully submitted,

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